

IDS Form PTO/SB/08: Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/623,431
				Filing Date	July 18, 2003
				First Named Inventor	Jay D. KRANZLER
				Art Unit	1614
				Examiner Name	Alicia R. HUGHES
Sheet	1	of	4	Attorney Docket Number	11013.0012-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1	4,708,834	11-24-1987	COHEN	
	2	4,710,384	12-01-1987	ROTMAN	
	3	4,734,285	03-29-1988	ALDERMAN	
	4	4,740,198	04-26-1988	THEEUWES	
	5	4,756,911	07-12-1988	DROST, et al.	
	6	4,761,501	08-12-1988	HUSBANDS, et al.	
	7	4,775,535	10-04-1988	LOWEY	
	8	4,781,919	11-01-1988	LIEBOWITZ	
	9	4,784,858	11-15-1988	VENTOURAS	
	10	4,792,448	12-20-1988	RANADE	
	11	4,795,327	01-03-1989	GAYLORD, et al.	
	12	4,795,642	01-03-1989	COHEN, et al.	
	13	4,795,645	01-03-1989	FRIEDMAN, et al.	
	14	4,798,725	01-17-1989	PATEL	
	15	4,800,083	01-24-1989	HOM, et al.	
	16	4,803,076	02-07-1989	RANADE	
	17	4,803,079	02-07-1989	HSAIO, et al.	
	18	4,806,359	02-21-1989	RADEBAUGH, et al.	
	19	4,816,262	03-28-1989	MCMULLEN	
	20	4,820,522	04-11-1989	RADEBAUGH, et al.	
	21	4,822,619	04-18-1989	EICHEL, et al.	
	22	4,824,678	04-25-1989	LINDAHL, et al.	
	23	4,832,957	05-23-1989	DEMPSKI, et al.	
	24	4,837,032	06-06-1989	ORTEGA	
	25	4,842,866	06-27-1989	HORDER, et al.	
	26	4,849,229	07-18-1989	GAYLORD, et al.	
	27	4,861,590	08-29-1989	GRODBERG	
	28	4,863,743	09-05-1989	HSIAO, et al.	
	29	4,871,548	10-03-1989	EDGREN, et al.	
	30	4,882,167	11-21-1989	JANG	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<i>Application Number</i>	10/623,431
				<i>Filing Date</i>	July 18, 2003
				<i>First Named Inventor</i>	Jay D. KRANZLER
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	Alicia R. HUGHES
Sheet	2	of	4	<i>Attorney Docket Number</i>	11013.0012-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	31	4,892,742	01-09-1990	SHAH	
	32	5,464,633	11-07-1995	CONTE, et al.	
	33	5,472,708	12-05-1995	CHEN	
	34	5,512,297	04-30-1996	BAICHWAL	
	35	5,532,244	07-02-1996	WONG, et al.	
	36	5,532,250	07-02-1996	WONG, et al.	
	37	5,776,969	07-07-1998	JAMES	
	38	5,885,616	03-23-1999	HSIAO, et al.	
	39	6,066,643	05-23-2000	PERRY	
	40	6,380,200	04-30-2002	MYLARI	
	41	6,964,962	11-15-2005	WONG, et al.	
	42	7,005,452	02-28-2006	DEREGNAUCOURT, et al.	
	43	2007-0225375	09-27-2007	KRANZLER, et al.	
	44	2008-0034101	02-07-2008	TRAN, et al.	
	45	2008-0058317	03-06-2008	RAO, et al.	
	46	2008-0058318	03-06-2008	RAO, et al.	
	47	2008-0293820	11-27-2008	RAO, et al.	

**Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	48	CA 2,431,041	07-11-2002	Pharmacia & Upjohn Co.		
	49	WO 97/10816	03-27-1997	Eli Lilly		
	50	WO 03/053426	07-03-2003	Cypress BioScience		
	51	WO 2004/009069	01-29-2004	Cypress BioScience		
	52	WO 2004/030633	04-15-2004	Cypress BioScience		
	53	WO 2007/038620	04-05-2007	Cypress BioScience		
	54	WO 2008/019388	02-14-2008	Cypress BioScience		
	55	WO 2008/021932	02-21-2008	Cypress BioScience		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	10/623,431
				Filing Date	July 18, 2003
				First Named Inventor	Jay D. KRANZLER
				Art Unit	1614
				Examiner Name	Alicia R. HUGHES
Sheet	3	of	4	Attorney Docket Number	11013.0012-00000

NONPATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
	56	AARON et al., "A review of the evidence for overlap among unexplained clinical conditions", Ann. Intern. Med. , Vol. 134, No. 9.2, (2001), pp. 868-881.	
	57	BOISSEVAIN et al., "Toward an integrated understanding of fibromyalgia syndrome. I. Medical and pathophysiological aspects", Pain, Vol. 45, No. 3, (1991), pp. 227-38.	
	58	BRILEY, "New hope in the treatment of painful symptoms in depression," Curr. Opin. Invest. Drugs, Vol. 4, No. 1, (2003), pp. 42-45. Abstract	
	59	GENDREAU et al., "Efficacy of Milnacipran in Patients with Fibromyalgia," The Journal of Rheumatology, Vol. 32, No. 10 (2005), pp. 1975-1984.	
	60	KASPER et al., "A placebo-controlled study of pregabalin and venlafaxine treatment of GAD", European neuropsychopharmacology, Vol.. 12, Suppl. 3, (October 2002), pp. S341-S342.	
	61	MEDLINE EMBASE 1998129084 1998 Milnacipran: New Preparation	
	62	MORET et al., "Sensitivity of the response of 5-HT autoreceptors to drugs modifying synaptic availability of 5-HT", Neuropharmacology, Vol. 27, No. 1, (1988), pp. 43-49.	
	63	WITTER et al., "Chronic pain and fibromyalgia: the regulatory perspective", Best Practice Res Clin Rheumatology, Vol. 17, No. 4, (2003), pp. 541-46	
	64	WOLFE et al., "A double-blind Placebo Controlled Trial of Fluoxetine in Fibromyalgia", Scand. J. Rheum., Vol. 23, No. 5, (1994), pp. 255-259.	
	65	WOLFE et al., "Health Status and Disease Severity in Fibromyalgia: Results of a Six-Center Longitudinal Study ", Arthritis Rheum., Vol. 40, No. 9, (1997), pp. 1571-1579	
	66	WOLFE et al., "Preference of Nonsteroidal Antiinflammatory Drugs Over Acetaminophen by Rheumatic Disease Patients", Arthritis Rheumatism, Vol. 43, No. 2, (2000), pp. 378-385.	
	67	WOLFE et al., "The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia", Arthritis Rheumatism, Vol. 33, No. 2 (1990) pp. 160-172	
	68	WOLFE et al., "The Prevalence and Characteristics of Fibromyalgia in General Population", Arthritis Rheumatism, Vol. 38, No. 1 (1995) pp. 19-28.	
	69	YOSHIMURA et al., "The involvement of the tetrodotoxin-resistant sodium channel Nav1.8 (PN3/SNS) in a rat model of visceral pain", J. Neurosci., Vol. 21, No. 21, (2001), pp. 8690-8696.	
	70	PCT/US02/40976 (WO 03/053426), International Search Report dated May 2, 2003.	
	71	PCT/US02/40976 (WO 03/053426), International Preliminary Report on Patentability/Written Opinion dated November 15, 2003	
	72	PCT/US03/23088 (WO 2004/009069), International Search Report dated December 11, 2003.	
	73	PCT/US03/23088 (WO 2004/009069), International Preliminary Report on Patentability/Written Opinion dated May 3, 2005.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<i>Application Number</i>	10/623,431
				<i>Filing Date</i>	July 18, 2003
				<i>First Named Inventor</i>	Jay D. KRANZLER
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	Alicia R. HUGHES
Sheet	4	of	4	<i>Attorney Docket Number</i>	11013.0012-00000

NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
	74	PCT/US03/031622 (WO 2004/030633), International Search Report dated June 3, 2004.	
	75	PCT/US03/031622 (WO 2004/030633), International Preliminary Report on Patentability/Written Opinion dated June 3, 2004.	
	76	PCT/US2006/037714 (WO 2007/038620), International Search Report dated August 23, 2007.	
	77	PCT/US2006/037714 (WO 2007/038620), International Preliminary Report on Patentability/Written Opinion dated April 1, 2008.	
	78	PCT/US2007/075555 (WO 2008/019388), International Search Report dated September 12, 2008.	
	79	PCT/US2007/075555 (WO 2008/019388), International Preliminary Report on Patentability/Written Opinion dated February 10, 2009.	
	80	PCT/US2007/075549 (WO 2008/021932), International Search Report dated September 19, 2008.	
	81	PCT/US2007/075549 (WO 2008/021932), International Preliminary Report on Patentability/Written Opinion dated February 10, 2009.	
	82	PCT/US2008/064471 (WO 2008/147843), International Search Report dated August 21, 2008.	
	83	PCT/US2008/064471 (WO 2008/147843), International Preliminary Report on Patentability/Written Opinion dated November 24, 2009.	
	84	U.S. Application No. 10/678,767, filed October 3, 2003, by Srinivas G. Rao et al.; Amendment accompanying request for continued examination dated September 3, 2009.	
	85	U.S. Application No. 10/678,767, filed October 3, 2003, by Srinivas G. Rao et al.; Non-Final Office Action dated January 8, 2010.	
	86	U.S. Application No. 11/535,237, filed Sept. 26, 2006, by Srinivas G. Rao et al.; Non-Final Office Action dated March 3, 2010.	
	87	U.S. Application No. 11/535,237, filed Sept. 26, 2006, by Srinivas G. Rao et al.; Restriction Requirement dated October 23, 2009.	
	88	U.S. Application No. 11/752,213, filed May 22, 2007, by Jay D. Kranzler et al.; Non-Final Office Action dated June 25, 2009.	
	89	U.S. Application No. 11/835,620, filed August 8, 2007, by Srinivas G. Rao et al.; Final Office Action dated July 2, 2009.	
	90	U.S. Application No. 12/035,820, filed February 22, 2008, by Jay D. Kranzler et al.; Final Office Action dated November 27, 2009.	
	91	U.S. Application No. 12/125,302, filed May 22, 2008, by Srinivas G. Rao et al.; Non-Final Office Action dated November 23, 2009.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.